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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,256	02/09/2004	Alfredo Berthel	PROCAPS 002C1	7158

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,256	BERTHEL ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-17 are being presented for examination.

Specification

2. The abstract of the disclosure is objected to because the phrase "selected from the group consisting of" is repeated. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "essentially contains" in claim 10 is a relative term, which renders the claim indefinite. The term "essentially contains" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of prior U.S. Patent No. 6,689,382 ('382 hereafter). This is a double patenting rejection.

Instant claim 1 is the same as claim 1 (more specifically claim 1 parts (a) and (b)) of '382. The limitations of a pharmaceutical formulation suitable for filling softgel capsules comprising a non-steroidal anti-inflammatory drug (NSAID) (selected from five groups) and a solvent system (comprising a polyoxyethylene ether, glycerin and water), including the percentages, formula of polyoxyethylene ether and groups of NSAIDs are recited in claim 1 parts (a) and (b) of '382.

Instant claim 2 is the same as claim 1 (particularly claim 1 part (c)) of '382. The limitation of an effective amount not to exceed the molar equivalent of the carboxylic acid function of an alkaline metal hydroxide selected from sodium hydroxide and potassium hydroxide are recited in claim 1 (particularly part (c)) of '382.

The limitation of ibuprofen as the propionic acid derivative of instant claims 3 and 4 are recited in claim 2 of '382.

The limitation of naproxen as the propionic acid derivative of instant claim 5 is recited in claim 3 of '382.

Regarding instant claim 6, the limitations of a pharmaceutical soft gelatin capsule comprising a NSAID selected from five groups and a solvent system (comprising a

polyoxyethylene ether, glycerin and water), including the percentages, formula of polyoxyethylene ether and groups of NSAIDs are recited in claim 4 of '382.

Regarding instant claim 7, the limitation of an effective amount not to exceed the molar equivalent of the carboxylic acid function of an alkaline metal hydroxide selected from sodium hydroxide and potassium hydroxide are recited in claim 4 of '382.

The limitation of ibuprofen as the propionic acid derivative of instant claim 8 is recited in claim 5 of '382.

The limitation of naproxen as the propionic acid derivative of instant claim 9 is recited in claim 6 of '382.

Regarding instant claim 10, the limitations of a pharmaceutical formulation with increased stability and bioavailability of an analgesic or anti-inflammatory agent, comprising a soft gelatin capsule with the analgesic or anti-inflammatory agent dissolved in a composition comprising glycofurol, glycerin, water and an effective amount not to exceed the molar equivalent of the carboxylic acid function of an alkaline metal hydroxide selected from sodium hydroxide and potassium hydroxide are recited in claim 7 of '382.

The limitation of ibuprofen as the propionic acid derivative of instant claim 11 is recited in claim 8 of '382.

The limitation of naproxen as the propionic acid derivative of instant claim 12 is recited in claim 9 of '382.

Since instant claims 1-12 claim the same invention as that of claims 1-9 of '382, they are not patentably distinct over each other.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,383,471).

The claimed invention is a pharmaceutical formulation for filling softgel capsules comprising: (a) a therapeutically effective amount of a non-steroidal anti-inflammatory drug (NSAID) selected from a group of propionic acid derivatives, acetic acid derivatives, fenamic acid derivatives, biphyenylcarboxylic acid derivatives, and oxicams, and (b) a solvent system comprising a polyoxyethylene ether, glycerin and water and an alkaline hydroxide.

Chen teaches a pharmaceutical composition suitable for use in oral dosage forms.

Chen does not expressly teach the percentages of the solvent components or the COX-2 inhibitors rofecoxib, valdecoxib, or parecoxib.

A person having ordinary skill in the art at the time the invention was made would have found instant claims 1, 6, 10, and 13 obvious over Chen. Chen teaches a pharmaceutical composition suitable for use in oral dosage forms, which includes a therapeutic agent, a carrier that includes solubilizers, and a neutralizing agent (Abstract). The therapeutic agents include ibuprofen, naproxen, and celecoxib (Col. 6,

lines 21, 35, and 40). These therapeutic agents are NSAIDs and celecoxib is a COX-2 inhibitor. Chen teaches that the carrier includes solubilizers such as ethers of polyethylene glycols such as tetrahydrofurfuryl alcohol PEG ether or glycofurol (Col. 31, lines 53-57). Soft gelatin capsules encapsulating the composition are the oral dosage forms (Col. 35, lines 3-5). Glycerin and water as optional components of a solvent system for a pharmaceutical agent are taught as a reference (Col. 2, line 7).

It would have been obvious to a person with ordinary skill in the art at the time the claimed invention was made to arrive at the claimed percentages during the process of routine experimentation in order to achieve the desired dosage of the active and capsule size as suggested by the teaching of Chen (which includes polyoxyethylene ether, glycerin, and water as solubilizer and solvent system components), and produce the instant invention.

The alkaline hydroxide claim limitation of instant claims 2, 7, and 10 would have been obvious to one with ordinary skill in the art over Chen. Chen teaches that sodium hydroxide and potassium hydroxide are examples of bases used as ionizing agents to deprotonate the acidic functional groups of the therapeutic agents (Col. 11, lines 10-14).

The limitations of ibuprofen and naproxen of instant claims 3, 4, 5, 8, 9, 11, and 12 would have been obvious to one with ordinary skill in the art over the Chen teaching of therapeutic agents including ibuprofen and naproxen (Col. 6, lines 35, and 40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical formulation for filling softgel

capsules comprising an NSAID, a solvent system, and an alkaline hydroxide, as suggested by Chen, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because this composition with the solubilizer enhances the solubility of the NSAID, and consequently enhances drug bioavailability.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,383,471), in view of Haskell (US 2002/0119200).

The teaching of Chen is stated above.

Chen does not expressly teach parecoxib, rofecoxib, and valdecoxib.

Haskell teaches drugs of low water solubility and includes analgesics and anti-inflammatories such as parecoxib, rofecoxib, and valdecoxib (Page 2, [0042], and Page 3, [0043]).

Instant claims 14 (with the limitation of rofecoxib), 15 (with the limitation of valdecoxib), 16 (with the limitation of celecoxib), and 17 (with the limitation of parecoxib), would have been obvious to one with ordinary skill in the art over the teaching of NSAIDs and celecoxib by Chen, in view of the teaching of the specific COX-2 inhibitors by Haskell.

One of ordinary skill in the art would have been motivated to do this because the COX-2 inhibitor (coxib) drugs are known NSAIDs and their inclusion in the composition as taught by Chen in view of Haskell would enhance the solubility and consequently the bioavailability of the drug.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

1. No claims are allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER